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) FMIA Docket No. 10-0018
) PPIA Docket No. 10-0018
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) Consent Decision
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The parties have agreed that this proceeding should be terminated by entry of this Consent Decision and have agreed to the following stipulations: The Respondent admits the findings of fact as set forth herein, and specifically admits that the Secretary has jurisdiction in this matter. The Respondent neither admits nor denies the remaining allegations and waives oral hearing and further procedure. Respondent and its owners, officers, directors, partners, successors, assigns, and affiliates waive any claim against complainant under the Equal Access to Justice Act of 1980 (5 U.S.C. § 504 *et seq.*) and waive other action against USDA or its employees in connection with this proceeding and the facts and events that gave rise to this proceeding. Respondent consents and agrees, for the purpose of settling this proceeding and for such purpose only, to the entry of this decision.

Findings of Fact

1. Respondent is now and at all times material herein, a business organized under the laws of the State of Delaware and operating as a meat and poultry processing facility at 3038 Pleasant Street, Riverside, California 92507.

2. Respondent is now, and was at all times material herein, a meat and poultry processing plant under a grant of inspection pursuant to the Poultry Products Inspection Act (21 U.S.C. §§ 451 et seq.)(PPIA) and the Federal Meat Inspection Act (21 U.S.C. §§ 601 et seq.) (FMIA) and designated as Official Establishment Number 1905M/9205P.

3. Anne M. Smalling, who resides at 12211 Technology Blvd., Austin, TX 78727, is, and at all times herein was, the chairman of Specialty Brands, L. P.

4. Respondent also does business as Windsor Foods, LP, and has also operated under the following names: Butcher Boy, Casa Marquez, Chef Mario, Fred's Frozen Foods, Imperial Kitchen, Little Juan, Little Juan Supreme, Marquez, Marquez Primera, Posada, Rotanelli Foods, Specialty Brands, Inc., Windsor Foods, and Windsor Frozen Foods.

5. On or about November 11, 2008, the Food Safety and Inspection Service performed Intensified Verification Testing at Respondent's federal establishment. On or about November 17 and 18, 2008, FSIS confirmed positive test results for *Listeria monocytogenes* on one (1) food contact surface and five (5) environmental surfaces in the post-lethality exposed Ready-to-Eat environment.

6. On or about March 10, 2009, the Food Safety and Inspection Service performed Intensified Verification Testing at Respondent's federal establishment. On or about March 16, 2009, FSIS confirmed positive test results for *Listeria monocytogenes* on one (1) food contact surface.

7. On or about March 10, 2009, the Food Safety and Inspection Service performed Intensified Verification Testing at Respondent's federal establishment and collected from Respondent's federal establishment samples of ready-to-eat beef and bean burritos produced by Respondent. On or about March 16, 2009, two samples confirmed positive test results for *Listeria monocytogenes*.

8. On or about March 10, 2009, it was determined that the *Listeria monocytogenes* found on non-food contact surfaces in November 2008 had an indistinguishable PFGE pattern from the *Listeria monocytogenes* found in product and on food contact surfaces in March 2009.

9. On or about September 14, 2009, the Food Safety and Inspection Service performed Intensified Verification Testing at Respondent's federal establishment. On or about September 21, 2009, FSIS confirmed positive test results for *Listeria monocytogenes* on one (1) food contact surface; two (2) environmental surfaces; and one (1) indirect contact surface in the post-lethality Ready-to-Eat environment.

10. Between November 11, 2008 and September 21, 2009, inspection services to Respondent were suspended on at least three occasions due to FSIS's determination that Respondent failed to comply with the requirements of the PPIA and the FMIA, and the regulations promulgated thereunder, which include, but are not limited to, the following:

(a) Repeated findings of *Listeria monocytogenes*, a microbial contaminant and adulterant in the post lethality Ready-to-Eat environment.

(b) Respondent failed to operate and maintain its business in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated, as required by Section 7(a) of the PPIA (21 U.S.C. §456(a)), Section 8 of the FMIA (21 U.S.C. § 608) and Part 416 of Title 9 of the Code of Federal Regulations (9 C.F.R. Part 416).

(c) Respondent failed to implement, maintain and monitor an adequate Hazard Analysis

Critical Control Point (HACCP) system to prevent insanitary conditions and to ensure that product is not adulterated, as required by Section 7(a) of the PPIA (21 U.S.C. §456(a), Section 8 of the FMIA (21 U.S.C. §608) and Part 417 of Title 9 of the Code of Federal Regulations (9 C.F.R. Part 417).

(d) Respondent failed to record and maintain such records as are necessary to insure against the production and shipment of adulterated products, as required by Section 11(b) of the PPIA (21 U.S.C. §460(b)), Section 202 of the FMIA (21 U.S.C. § 642) and Parts 416 and 417 of Title 9 of the Code of Federal Regulations (9 C.F.R. Parts 416 and 417).

(e) Respondent failed to conduct adequate operating procedures to prevent environmental, product contact, and non-product contact surfaces and product contamination with *Listeria monocytogenes*, as required by Part 430 of Title 9 of the Code of Federal Regulations (9 C.F.R. Part 430).

Conclusion

The parties having admitted the jurisdictional facts and the parties having agreed to the entry of this decision, this decision will be entered.

Order

Federal inspection services under the FMIA and the PPIA are withdrawn from Respondent, its owners, officers, directors, partners, successors, affiliates, and assigns, directly or through any corporate device, for a period of two (2) years beginning on the effective date of this Order. Provided, however, the withdrawal of inspection services shall be held in abeyance, and inspection services shall be provided to Respondent for so long as the conditions set forth below, in addition to all other requirements for applicable inspection services, are met:

1. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent shall demonstrate compliance with all applicable FSIS statutory and regulatory requirements, including, but not limited to, 9 C.F.R. Parts 416, 417, and 430, upon a review and

examination of (a) Respondent's Sanitation Performance Standards (SPS), Sanitation Standard Operating Procedures (SSOP), Hazard Analysis and Critical Control Point (HACCP) system, *Listeria monocytogenes* (*Lm*) sampling and testing program, and other written sanitation, process controls, and sampling or testing programs; and (b) the physical and sanitary conditions of Respondent's establishment.

2. During the period of this Order, within its discretion, FSIS may conduct examinations of records, Intensified Verification Testing (IVT), and other verification and monitoring activities to ensure Respondent's compliance, implementation, and the effectiveness of its SPS, SSOP, HACCP, *Lm* sampling and testing program and other systems, plans, and records required by the FMIA, PPIA, the regulations, and this Order.

Sanitation Performance Standards

3. Within ten (10) calendar days of the resumption of inspection services, and subject to verification by FSIS, Respondent shall develop written procedures, including monitoring, corrective action, and recordkeeping procedures that Respondent will implement to operate and maintain its establishment, including its premises, facilities, equipment, and outside premises, in a manner sufficient to prevent the creation of insanitary conditions and practices, comply with the requirements of the SPS regulations (9 C.F.R. part 416), and ensure that meat and meat products, and poultry and poultry products, prepared, stored, and packed are not adulterated.

4. Upon the resumption of inspection services, and subject to verification by FSIS, Respondent shall:

(a) operate and maintain, at all times, its establishment, including its premises, facilities, equipment, and outside premises, in a manner sufficient to prevent the creation of insanitary conditions and practices, comply with the requirements of the SPS regulations, and ensure that meat and meat food products, and poultry and poultry products, are not adulterated; and

(b) assess its written SPS procedures to evaluate their effectiveness, and make necessary improvements, corrective actions, repairs to the establishment buildings, structures, rooms, and compartments to ensure that that they are kept in good repair, and sufficient size to allow for processing, handling, and storage of product in a manner to ensure and maintain sanitary conditions.

Planned Improvement Program

5. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondents shall develop a "Planned Improvement Program" (PIP) to ensure that the entire structure of the facility, to include its rooms and compartments, are of sound construction and that all equipment is maintained in proper working order and kept in good repair.

6. Upon the resumption of inspection services, and subject to verification by FSIS, Respondents shall:

- (a) implement and maintain its PIP as required in this Order;
- (b) document findings and corrective actions to address structural and/or mechanical repairs and/or improvements to their facility under the PIP to ensure the entire structure of the facility, to include its rooms and compartments are of sound construction, and that all equipment is maintained in proper working order and kept in good repair; and
- (c) make all records associated with the PIP available to FSIS for review and/or copying immediately upon request.

Sanitation Standard Operating Procedures

7. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent shall:

- (a) develop written sanitation standard operating procedures (SSOP) to describe the monitoring activities, recordkeeping, and other procedures Respondent will conduct, implement,

and maintain, on a daily and ongoing basis, before, during, and after operations, in accordance with this Order and regulatory requirements, 9 C.F.R. part 416, to ensure sanitary conditions and prevent product adulteration; and

(b) address specific procedures within the written SSOP, including the following:

- (i) cleaning and sanitizing equipment and utensils;
- (ii) written instructions for complex equipment use and methods of cleaning;
- (iii) proper handling, storage, denaturing, and disposal of inedible products;
- (iv) re-conditioning of contaminated product; and (v) employee hygienic

practices.

8. Upon the resumption of inspection services, and subject to verification by FSIS, Respondent shall:

(a) implement and maintain, on a daily and ongoing basis, its SSOP system as provided in this Order and regulatory requirements of 9 C.F.R. Part 416 to ensure sanitary conditions and prevent product adulteration; and

(b) implement corrective and preventative actions as required by 9 C.F.R. § 416.15 and evaluate the effectiveness of its SSOP, and implement necessary modifications as required by 9 C.F.R. § 416.14 to ensure that regulatory requirements for the maintenance of sanitary conditions and the production and distribution of safe, wholesome, not adulterated, and properly labeled products in commerce are met.

Hazard Analysis and Critical Control Point (HACCP) Plan

9. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent shall:

(a) reassess its HACCP systems to describe each system of process controls and procedures that Respondent will implement and utilize on a daily and on-going basis to control

and prevent the introduction of food safety hazards in their meat or poultry products. These plans shall address specific process controls and procedures within Respondent's HACCP system(s) (i.e. *Listeria monocytogenes* in post lethality process steps), including, but not limited to, the following:

- (i) measures to identify the biological, chemical, and physical food safety hazards reasonably likely to occur at each process step, or elimination of such hazards, or their reduction to undetectable levels;

- (ii) measures to address *L. monocytogenes* as a hazard reasonably likely to occur;

and

- (iii) measures to eliminate or reduce and control the level of *L. monocytogenes* to prevent contamination of Respondent's finished Ready-to-Eat (RTE) product, food contact surfaces, and non-contact environmental surfaces; and

- (b) include all decision making documents for the plan(s), including its hazard analysis or analyses, validation protocols, and all parameters used in said protocols, and data to support the food safety system(s).

10. Upon resumption of inspection services, and subject to the verification of FSIS, Respondent shall:

- (a) implement, validate, and maintain on a daily and ongoing basis the HACCP system(s) and plan(s), as provided in this Order, in accordance with the requirements of 9 C.F.R. Part 417;

- (b) implement timely and appropriate corrective and preventive actions and reassess and modify its HACCP systems and plans as necessary to ensure that the regulatory requirements for the control and prevention of pathogens and the production and distribution of wholesome, unadulterated, and properly labeled products in commerce are met, as required by and consistent with 9 C.F.R. Part 417; and

(e) conduct ongoing assessment, validation, and testing of the adequacy of the critical control points, critical limits, monitoring, and record-keeping procedures, and corrective actions set forth in the HACCP system(s) and plan(s), to ensure that Respondent's food safety system remains validated over time, as required by 9 C.F.R. Part 417.

Listeria monocytogenes Sampling and Testing Program

11. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent shall develop a written *L. monocytogenes* sampling and testing program for its RTE products in accordance with 9 C.F.R. Part 430 and, at a minimum, shall include:

- (a) routine and intensified product sampling and testing;
- (b) one of the three alternatives for the production of post-lethality exposed RTE product;
- (c) testing for product, direct product contact surfaces, indirect product contact surfaces, and non product contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;
- (d) frequency for which testing will be done;
- (e) identification of the size and location of the sites that will be sampled;
- (f) an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes*, or an indicator organism, is maintained;
- (g) random sampling for all facility sites and production days that will give an equal opportunity of selection for all sites and times; and
- (h) hold and test procedures following a positive test of a product or direct product contact surfaces for *L. monocytogenes* or an indicator organism and assess any surface that may come in contact with product;
- (i) procedures to notify FSIS of all testing and sampling results, including presumptive positives, upon receipt of samples results; and
- (j) designate in writing, subject to the concurrence of the FSIS, one full time person and

one alternate who shall be responsible for conducting sampling or other activities under Respondent's written *L. monocytogenes* program and 9 C.F.R. Part 430.

Initial Start-up Production Sampling

12. Upon resumption of inspection services, and subject to verification by FSIS, Respondent shall implement a seven (7) production day initial start-up production period intensified sampling and testing production schedule, to include:

- (a) full establishment operations and production of RTE products;
- (b) intensified testing for product, direct product contact surfaces, indirect product contact surfaces, and non product contact surfaces during the seven (7) production day initial start-up production period to ensure no positive *L. monocytogenes* findings;
- (c) the implementation of hold and test procedures for all RTE products produced until negative results are received for the seven (7) production days;
- (d) testing and sampling for *L. monocytogenes* at the following frequency: (i) For "direct product contact surfaces" random sampling and testing for fifteen (15) sites per line per production day; (ii) For "indirect product contact surfaces" random sampling and testing for nine (9) sites per line per production day; and (iii) For "non product contact surfaces" random sampling and testing for nine (9) sites per line per production day; and (iv) Ten (10) random samples for finished product from each line throughout the production day; and
- (e) holding procedures for all products produced during the seven (7) production days initial start-up production period until all negative results are received for all seven (7) production days.

13. In the event of any positive *L. monocytogenes* test result for RTE product or direct product contact surfaces at any time during the seven (7) production day initial start-up production period, Respondent shall:

- (a) immediately suspend operations;
- (h) destroy all products produced and held during the seven (7) production day initial start-up period;
- (c) take necessary corrective and preventative measures to address the *L. monocytogenes* positive finding;
- (d) reevaluate its *L. monocytogenes*, SSOP, HACCP, and other programs or plans to determine if modifications need to be made to address preventative and corrective measures;
- (e) document appropriate corrective and preventative actions, including re-swabbing of positive sampling site and surrounding area;
- (f) retrain employees in the *L. monocytogenes* program or other programs or procedures if in Respondent's reassessment it is determined that the contamination was due to employee practices or actions;
- (g) document any employee training; and
- (h) submit Respondent's proposed corrective actions, preventative measures, and any changes to its SSOP, HACCP, *Lm* sampling and testing program, or other systems, programs, or plans to FSIS for review, verification, and concurrence prior to resumption of operations.

14. In the event of any positive *L. monocytogenes* test results for indirect product contact surfaces or non product contact surfaces, Respondent shall:

- (a) submit its proposed corrective actions, preventative measures, including the re-swabbing of positive sampling site and surrounding area, and any changes to its SSOP, HACCP, *Lm* sampling and testing program, or other systems, programs or plans to FSIS for review, verification, and concurrence; and
- (b) continue to hold all product produced until the successful completion of the entire initial start-up period, negative results are received and all information regarding all testing has

been provided to FSIS for review, verification, and concurrence. FSIS will then make a determination concerning the disposition of the product based upon the information provided by the Respondent regarding the sanitary conditions of the facility and the wholesomeness of the product.

15. Respondent shall, in the event of any positive *L. monocytogenes* test results as described in paragraphs 13 and 14 of this Order re-start its seven (7) production day initial start-up production period intensified sampling and testing program as provided in paragraph 12 of this Order until all negative results are received for all seven (7) production days.

16. Respondent may in the event of the successful completion of the initial start-up period for all seven (7) production days: (i) ship all RTE products produced during the seven (7) production day initial start-up production; and (ii) continue operations, testing, and sampling for *L. monocytogenes* under their proposed routine sampling procedures.

Routine and Intensified Sampling and Testing

17. Respondent's routine and intensified production sampling and testing shall, at a minimum, include:

- (a) random testing and sampling for all facility sites and production days that will give an equal opportunity of selection for all sites and times;
- (b) descriptions of the size and location of the sites that will be sampled;
- (c) an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes*, or indicator organism, is maintained; and
- (d) procedures to ensure that any product placed on hold pending test results are held until negative results are received.

18. In the event of any positive *L. monocytogenes* test result for RTE product and direct product contact surfaces, Respondent shall suspend RTE operations, and prior to resumption

Respondent shall:

- (a) take all necessary corrective and preventative measures to address the *L. monocytogenes* positive findings;
- (b) reassess their *L. monocytogenes*, SSOP, and HACCP programs to determine if modifications need to be made to address preventative and corrective measures;
- (c) document appropriate corrective and preventative actions, including re-swabbing of positive sampling site and surrounding area;
- (d) retrain employees in the *L. monocytogenes* program if in Respondent's reassessment it is determined that the contamination was due to employee practice or actions;
- (e) document any employee training; and
- (f) include a temporary Critical Control Point (CCP) for sanitation; and
- (g) submit its proposed corrective actions, preventative measures and any changes to its SSOP, HACCP, *Lm* sampling and testing program or other systems, programs or plans to FSIS for review and verification.

19. In the event of a positive *L. monocytogenes* findings on indirect product contact surfaces or non product contact surfaces, Respondent shall:

- (a) submit its proposed corrective actions, preventative measures, and
- (b) any changes to its SSOP, HACCP, *Lm* sampling and testing program or other systems, programs or plans to FSIS for review and verification

20. Respondent shall notify the FSIS District Manager and/or designee of any changes or modifications to its SSOP, HACCP, *Lm* sampling and testing program or other systems, programs or plans, and all associated recordkeeping forms, as documented under paragraphs 18 and 19.

21. Respondent shall in the event of any positive *L. monocytogenes* test results as

described in paragraph 18 or 19 of this Order, implement an intensified sampling and testing program until all negative results are received.

22. Respondent shall document and maintain all sample laboratory results and records regarding the implementation and monitoring of its *L. monocytogenes* program, including corrective actions, regulatory records, and preventive measures, in accordance with 9 C.F.R. § 417.5, and make these plant records available to FSIS personnel for review and/or copying immediately upon request.

Employee Training

23. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent shall develop a training program for all current employees and future hires involved in the preparation, processing, and/or production of meat and poultry products to ensure that employees are trained in aspects of food safety measures and regulatory requirements, including the requirements of the SPS, SSOP, HACCP, *L. monocytogenes* sampling and testing, recordkeeping procedures, and Good Manufacturing Practices (GMP's), relevant to each employee's position.

24. Within thirty (30) calendar days of the effective date of this Order and subject to verification by FSIS, Respondent shall train all such current employees consistent with the requirements of paragraph 23 of this Order.

25. Respondent shall train and educate any new employee(s), consistent with the requirements of this Order, within thirty (30) calendar days of employment

26. Respondent shall conduct annual training for all employees and management personnel involved in the preparation, processing, and/or production, of meat and poultry products, current and new, consistent with the requirements of this Order.

27. Respondent shall document and maintain all training and education materials,

training records, test results, and other materials for all training required by paragraphs 23 thru 26 of this Order and make these records available to FSIS personnel for review and/or copying immediately upon request.

Third Party Audits

28. Respondent shall, upon resumption of inspection services, cause to be made, by a qualified, independent third-party, written audits of:

(a) Respondent's implementation, monitoring, and maintenance of its sanitation, SSOP, HACCP and other process control, *Lm* sampling and testing, and other programs;

(b) the effectiveness of Respondent's sanitation, SSOP, HACCP, and other process control, *Lm* sampling and testing, and other programs to ensure food safety;

(c) Respondent's compliance with FSIS statutory and regulatory requirements,

(d) Respondent's compliance with the terms of this Order;

(e) any findings and recommendations of the independent third-party.

29. The audits shall be conducted, at least as frequently, as follows:

(a) the first audit shall be conducted within ninety (90) calendar days from the effective date of this Order; and

(b) subsequent audits shall be conducted every (180) calendar days thereafter for the duration of the Order.

30. Respondent shall prepare, for each audit conducted, a written response to the audit findings and recommendations. Respondent's written response shall identify:

(a) any modifications to its SSOP, HACCP, *Lm*, or other programs or plans;

(b) any corrective actions implemented;

(c) any other actions implemented or planned in response; and

(d) supportable information for any decision by Respondent to not implement any audit recommendation.

31. Respondent shall submit a copy of each third-party audit, a copy of Respondent's written response, or other documents relative to the audit to the Director of Evaluation and Enforcement Division (hereinafter Director, EED) for review and concurrence within (30) calendar days after each audit is completed.

Recordkeeping

32. Respondent shall maintain full, complete and accurate written records of (a) all records required to be maintained by the FMIA, the PPIA, and the regulations; and (b) all SPS, SSOP, HACCP, *Lm* sampling or testing of products and other systems, plans and records required by the FMIA, PPIA, the regulations, and this Order. Respondents shall make all such records available to FSIS representatives for review and/or copying immediately upon request.

33. Respondent shall notify the FSIS District Manager and/or designee of any changes or modifications to its SSOP, HACCP, *Lm* sampling and testing program or other systems, programs or plans, and all associated recordkeeping forms as required by the regulations or this Order.

General Provisions

34. Respondent or any of its owners, officers, directors, partners, managerial employees, agents, successors, affiliates, or assigns, shall not:

(a) violate any section of the FMIA, the PPIA, State or local statutes involving the preparation, sale, transportation or attempted distribution of any adulterated or misbranded meat or poultry products;

(b) willfully make, or cause to be made, any false entry in any account, record, or memorandum kept by Respondent in compliance with applicable Federal or State statutes or regulations; or willfully neglect or fail to make full, true and correct entries in such accounts,

records or memoranda; or fail to keep such accounts, records or memoranda that fully and correctly disclose all transactions in Respondent's business;

(c) commit any felony or fraudulent criminal act that results in a conviction; or

(d) assault, intimidate, or interfere with; or threaten to assault, intimidate, or interfere with any program employee in the performance of his or her official duties under the FMIA and PPIA; or

(e) for positions that would be considered managerial or a responsibly connected as defined in the FMIA and PPIA, knowingly hire or add any new individual who has been convicted, in any Federal or State court, of any felony, or more than one misdemeanor based upon the acquiring, handling, or distributing of unwholesome, mislabeled or deceptively packaged food, or fraud in connection with transaction in food; and shall immediately terminate its connection with any such individual when that individual's conviction becomes known to Respondent.

Enforcement Provisions


35. The Administrator, FSIS, may summarily withdraw inspection services upon a determination by the Director EED, or his or her designee, that one or more conditions set forth in paragraphs 1 through 34 of this Order have been violated. It is acknowledged that Respondent retains the right to request an expedited hearing pursuant to the rules of practice concerning any violation alleged as the basis for a summary withdrawal of inspection services. Nothing contained in these provisions prevents the right of Respondents to appeal the decision of an FSIS employee to his/her immediate supervisor pursuant to 9 C.F.R. §306.5 or §381.35.


36. Nothing in this Order shall preclude (a) any future criminal, civil, regulatory or administrative action authorized by law, regulation or otherwise, including, but not limited to any

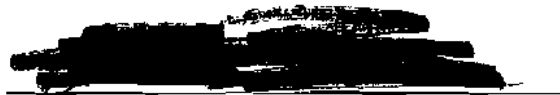
action under the FSIS rules of practice (9 C.F.R. Part 500), or (b) the referral of any matter to any agency for possible criminal, civil, or administrative proceedings.

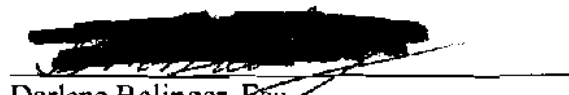
37. If any provision of this Consent Decision is declared invalid, such declaration shall not affect the validity of any other provision herein.

The provisions of this Consent Decision Order shall be applicable for a period of two (2) years and shall become effective upon issuance by the Administrative Law Judge.

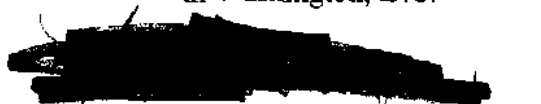

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United States Department of Agriculture
Office of the General Counsel

Issued this 16th day of February 2010
in Washington, D.C.


ADMINISTRATIVE LAW JUDGE